

**In the Arbitration under the Arbitration Rules of the
United Nations Commission on International Trade Law and
the North American Free Trade Agreement
(Case No. UNCT/14/2)**

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

**SECOND EXPERT REPORT OF NORMAN V. SIEBRASSE
Professor of Law, University of New Brunswick**

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I. Introduction

1. I have reviewed the Report of Mr. Ronald Dimock and the materials cited therein. Mr. Dimock and I appear to agree on how the current Canadian law of utility was applied to invalidate the patents at issue, and Mr. Dimock does not dispute that the patents would have been valid but for these controversial aspects of the current law. The only disputed question is whether the law that was applied to invalidate the patents is new.

2. Nothing in Mr. Dimock's Report or the cited materials causes me to change the conclusions stated in my first Report, in which I explained that since 2002 the Canadian law of utility has changed in three aspects: utility is now assessed against "the promise of the patent";¹ the heightened standard for utility imposed by the promise of the patent may lead to heightened evidentiary scrutiny, yet post-filing evidence of utility is no longer admissible; and there is a new requirement to disclose evidence supporting sound prediction of utility in the patent itself.

3. In contrast, Mr. Dimock asserts that these aspects of Canada's utility requirement, referred to in my first Report in the collective as the "Promise Utility Doctrine", have remained virtually unchanged for decades. In this overview, I outline my main points of disagreement with Mr. Dimock's assertions, focusing on the central question of whether the law, as reflected in the jurisprudence, has changed.

4. Under the first aspect of Canada's current Promise Utility Doctrine, the courts construe the patent to determine the "promise of the patent", against which utility is assessed. This promise analysis has two features which distinguish it from the standard against which utility was previously assessed: (1) under the promise of the patent, utility is assessed against a promise or promises derived from the disclosure of the patent; and (2) this promised utility is higher than the scintilla of utility that otherwise would be required to support a patent. There are many recent cases, including the patents at issue, in which a patent has been held invalid as a result of utility being assessed against an elevated promise derived from the disclosure. If, as Mr.

¹ In my first Report, I explained that the standard of utility now has two branches. *See* First Expert Report of Norman V. Siebrasse ("Siebrasse First Report") at ¶ 41. The courts find that the patent does not "promise" any specific result, a "mere scintilla" of utility will suffice. However, if the courts hold that there is a "promise" in the patent, the utility of the invention is assessed against that promise. I referred to the latter as the "promise analysis" or the "promise of the patent."

Dimock asserts, this aspect of the utility requirement were long-established, one would expect to see a patent invalidated on this basis in at least some cases prior to 2005. Yet Mr. Dimock does not cite any older cases in which a patent is held invalid against an elevated promise derived from the disclosure.

5. Mr. Dimock relies primarily on the Supreme Court of Canada decision in *Consolboard* to contend that the current practice of construing elevated promises of utility is long-established. *Consolboard* does not reflect the promise analysis seen in Canada today. The promise analysis had not been applied in any case before *Consolboard* and was not applied in *Consolboard* itself. The Canadian cases cited and discussed in *Consolboard* were, if anything, contrary to a promise analysis. Although the decision issued in 1981, *Consolboard* was not cited in support of a promise analysis until nearly 25 years later, in 2005. If *Consolboard* were good authority for the promise aspect of Canada's current Promise Utility Doctrine, surely it would have been cited to that effect at some time in the two decades after it was decided. In any case, utility was not directly at issue in the 1981 *Consolboard* decision, which concerned the disclosure requirement, and the passage in the case that Mr. Dimock relies on certainly cannot be taken to have approved or imported into Canadian law anything resembling the promise aspect of Canada's current Promise Utility Doctrine. *Consolboard* reiterated that utility is a low bar, under which it is enough to "[afford] the public a useful choice."

6. Mr. Dimock relies on a total of four additional cases to support his contention that the promise of the patent was applied in prior law, but not one of these cases applies such an analysis. Two of the cases (*Mobil Oil* and *Unilever*) are, if anything, contrary to the promise of the patent, as the court actually refused to consider that statements in the disclosure portion of the patent could amount to a promise against which utility must be assessed. *New Process Screw* was a case in which the invention as claimed was inoperable. *Amfac* reflects a different principle of patent law, namely, the rule that an inventor cannot claim more broadly than the invention that is actually invented.

7. With respect to the second aspect of Canada's current Promise Utility Doctrine – the inadmissibility of post-filing evidence – Mr. Dimock asserts that "it has long been understood in Canadian patent law that post-filing evidence is not available to prove that an inventor had made the invention by the filing date of the patent application (including

satisfaction of the utility requirement).”² However, the *only* case cited by Mr. Dimock as supporting this proposition is *AZT* itself – the very case which changed the law on this point.

8. In my first Report, I cited numerous cases prior to *AZT* in which the courts considered post-filing evidence of utility. Mr. Dimock attempts to explain away these cases on the basis that such evidence was only admitted to show that the invention had utility at the time of challenge, as opposed to being admitted to show that the utility requirement was met when the patent was sought.³ This is contradicted by a number of pre-*AZT* decisions that admitted post-filing evidence to show that the invention met the utility requirement as of the filing date. Conversely, Mr. Dimock has not cited any cases at all prior to *AZT* in which post-filing evidence was held to be inadmissible for the purpose of establishing utility. If that rule were as well-established as Mr. Dimock says, surely it would have been possible to find at least one case applying it.

9. The third new aspect of the current Canadian Promise Utility Doctrine is that when utility is based on a sound prediction, the evidence establishing that the prediction is sound must be disclosed in the patent itself (even though the evidence need not be so disclosed if it is used to demonstrate utility) . I explained in my first Report that this heightened disclosure requirement for sound prediction was introduced by the 2008 *Raloxifene* decision, which interpreted the *AZT* decision.⁴ Mr. Dimock asserts that the requirement is long-established, but he cites only one Canadian case prior to *AZT*, namely the Patent Appeal Board decision in *Monsanto*. While the Patent Appeal Board decision in *Monsanto* does appear to embrace that heightened disclosure requirement, that decision was reversed by the Supreme Court of Canada. Remarkably, Mr. Dimock nonetheless asserts that the Supreme Court somehow endorsed a heightened disclosure requirement.⁵ Mr. Dimock also cites an English case, *Olin Mathieson*. In that case, evidence that was not disclosed in the patent was actually accepted as important

² Expert Report of Ronald E. Dimock (“Dimock Report) at ¶ 102

³ Dimock Report at ¶ 105.

⁴ *Eli Lilly Canada Inc. v Apotex Inc.*, 2008 FC 142, ¶ 164, 63 C.P.R. (4th) 406 (C-115), aff’d 2009 FCA 97, ¶ 14, 78 C.P.R. (4th) 388 [*Raloxifene*] (C-119), discussed in the Siebrasse First Report at ¶ 64; see *Apotex Inc. v Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 [*AZT*] (C-213).

⁵ Dimock Report at ¶¶ 135-37.

evidence of utility. Again, if the heightened disclosure requirement were so well-established, surely it would be possible to find at least one case actually applying it.

10. One case that clearly does apply a heightened disclosure rule for sound prediction is *Raloxifene* itself. Mr. Dimock asserts that “on a careful reading of the case, it becomes apparent that *Raloxifene* was well considered and reasoned, and follows the same principles applied more than 25 years prior in *Monsanto*.”⁶ If *Raloxifene* really did apply the same principles as *Monsanto*, it is remarkable that the trial judge in that case did not recognize that fact. Indeed, no Canadian judicial decision has ever linked the heightened disclosure requirement to the *Monsanto* decision.

11. Federal Court decisions dealing with sound prediction after *AZT* but prior to *Raloxifene* did not acknowledge any heightened disclosure requirement. If that point were well established by the Supreme Court in *Monsanto*, it is very surprising that neither the courts nor counsel in those cases were aware of it.

12. The various aspects of the Promise Utility Doctrine are, therefore, a new development in Canadian law, contrary to what Mr. Dimock asserts in his Report. All three aspects are applied together as part of Canada’s current utility requirement and operate as a unitary whole. In combination, their effect is to set a much higher bar to meet for utility than under prior law.

II. Canada’s Traditional Patent Utility Test Changed Dramatically After *AZT*

A. Utility Is Now Assessed Against the Promise of the Patent

13. The first change in Canada’s utility requirement discussed in my first Report is that the standard against which utility is assessed now has two branches: if the court finds a promise in the patent, utility is assessed in terms of that standard; if not, a “mere scintilla” of utility will suffice.⁷ Mr. Dimock does not dispute that this promise analysis may result in a

⁶ Dimock Report at ¶ 140, referring to *Monsanto Co. v Commissioner of Patents*, [1979] 2 S.C.R. 1108, 42 C.P.R. (2d) 161, rev’g 34 C.P.R. (2d) 1 (FCA) [*Monsanto*] (C-61).

⁷ Siebrasse First Report at ¶ 41, quoting *Eli Lilly Canada Inc. v Novopharm Ltd.*, 2010 FCA 197, ¶ 76 [*Olanzapine (No. 1)*] (C-46).

higher standard for utility, but argues that the analysis is neither new nor arbitrary. However, the prior cases cited by Mr. Dimock do not constitute examples of the promise of the patent, but rather exemplify other uncontroversial aspects of patent law. Mr. Dimock is furthermore incorrect in stating that the courts have always undertaken to construe the promise of the patent, and that there is a sound policy basis for doing so.

(i) What Is the Promise of the Patent?

14. It is important to understand the characteristics of the promise aspect of Canada's current Promise Utility Doctrine in order to evaluate Mr. Dimock's assertion that it was applied in prior law. Under the mere scintilla test, the standard for utility does not vary based on particular statements about the usefulness of the invention made in (or implied from) the patent. The requisite degree of utility is always the same: a "mere scintilla" will do. In contrast, under the promise of the patent, the standard for utility depends on the particular statements made in the disclosure (regardless of what is claimed), and may be much higher than the scintilla that would otherwise be required to support a patent. For example, the atomoxetine (Strattera) patent in issue was held to a standard of clinical efficacy in the longer term,⁸ even though pharmaceutical patents are often sought well before clinical trials are conducted, and, as Mr. Dimock acknowledges, the minimum utility required to support a patent is far less than that required for regulatory approval.⁹

15. The fact that a court looks to the disclosure to see what the invention is useful for does not mean the court is applying the promise analysis. The patent will state the utility of the invention in the disclosure if the utility of the claimed invention is not apparent. For example, if the claimed invention is a new chemical compound with pharmacological activity and that activity is not apparent to a skilled person, the patent disclosure will state the pharmacological activity. But all that is required under the traditional test is that the invention have a "scintilla" of utility (*i.e.* the stated pharmacological activity). This is true no matter what else is said (or can be

⁸ Siebrasse First Report at ¶¶ 94, 102. The olanzapine (Zyprexa) patent in issue was held to a standard that required "marked superiority" and "a better side effects profile" than prior known antipsychotics, based on the promise of the patent as construed by the Court.

⁹ Dimock Report at ¶ 187.

implied from) the disclosure about other potentially useful characteristics of the invention, including, for example, that the compound may be useful for treating certain conditions.

16. In contrast, applying the promise of the patent, the courts will scour the disclosure to determine what specific “promises” have been made about the usefulness or performance of the invention, and these “promises” then determine the degree of utility that is required.¹⁰ So, if a patent identifies that the claimed compound has a certain pharmacological activity that may be useful for treating various conditions, under the mere scintilla test, the pharmacological activity is sufficient to establish utility. However, according to the promise of the patent, if other statements in the disclosure about the potential use of the compound to treat various human conditions or its degree of effectiveness in treating these conditions (*e.g.* long-term treatment, fewer side effects) are construed to be “promises”, then it is this elevated standard of utility that must be met, even though pharmacological activity alone would be enough to support a valid patent under the mere scintilla standard.

17. Consequently, the fact that courts sometimes look to the disclosure to identify the utility of the invention does not establish that the promise of the patent is long-established as part of Canada’s utility law.¹¹ Nor does the use of the word “promise” to describe the invention’s utility necessarily signal the application of the promise analysis. In prior case law, this word was commonly used merely to describe the apparent or stated utility of the invention, *i.e.* “the promised result”, and did not at all involve the type of analysis seen today, under which the court undertakes to construe promises from the patent disclosure that become the standard against which utility is assessed.¹²

18. It is clear law today in Canada that a patent may be held invalid because of a statement, construed as a promise, which is found in the disclosure and which is more onerous

¹⁰ More precisely, the promise of the patent sets the standard for utility whenever a promise is found. While this commonly concerns the degree of utility – how good the invention is at treating glaucoma, how severe the side-effects are – the promise of the patent may in principle also result in the invention being required to have multiple uses, even though one would be enough to support a patent under the traditional test: see *e.g.* *Lundbeck Canada Inc. v Apotex*, 2009 FC 146, ¶ 135 (though the court held on the facts that multiple uses were not promised) (C-442).

¹¹ Cf. Dimock Report at ¶ 88.

¹² See Siebrasse First Report at ¶¶ 75-80.

than the minimum utility necessary to support a patent.¹³ In assessing whether the law has changed, the key question is whether, under prior law, a patent with sufficient utility to support a patent (*i.e.* a mere scintilla) could nonetheless have been invalidated for failure to achieve a promise of even greater utility construed by the courts from the disclosure. The answer is “no.”

(ii) The Sources Relied on by Mr. Dimock Do Not Provide Authority for the Promise of the Patent Aspect of Canada’s Promise Utility Doctrine

a) *Consolboard* Did Not Apply the Promise of the Patent

19. That *Consolboard* did not affirm or establish the promise of the patent aspect of Canada’s Promise Utility Doctrine is confirmed by its subsequent treatment. *Consolboard* was routinely cited for its pronouncements on the disclosure requirement from the time it was decided, and it remains the leading case even today. For many years after it was decided *Consolboard* was also a leading case on claim construction, and it was routinely cited in that context as well.¹⁴ In contrast, prior to 2005 *Consolboard* was rarely cited for its observations regarding the law of utility,¹⁵ and it was never cited for the promise analysis in particular. If it were good authority for the promise aspect of Canada’s current Promise Utility Doctrine, *Consolboard* would surely have been cited to that effect at some time in the two decades after it was decided, but it was not.

20. Nevertheless, Mr. Dimock asserts that the decision of the Supreme Court of Canada in *Consolboard* is authority for the courts’ current application of the promise of the patent.¹⁶ This assertion depends entirely on the following statement from *Consolboard*:

There is helpful discussion in *Halsbury’s Laws of England*, (3rd ed.), vol. 29, at p. 59, on the meaning of “not useful” in patent law. It means “that the invention will

¹³*Sanofi-Aventis v Apotex Inc.*, 2013 FCA 186, ¶ 54, 114 C.P.R. (4th) 1 [*Plavix*] (C-47).

¹⁴ It has now been largely supplanted as the leading authority on claim construction by the more recent decisions in *Free World Trust v Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 (C-189) and *Whirlpool Corp. v Camco Inc.* 2000 SCC 67 [2000] 2 S.C.R. 1067 [*Whirlpool*] (C-254).

¹⁵ Mr. Dimock states that “*Consolboard* is the leading authority on the standard of an invention’s utility.” Dimock Report at ¶ 61. That is not correct. It is now cited for the promise doctrine, but it was rarely cited for utility prior to 2005.

¹⁶ Dimock Report at ¶¶ 56-60.

not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do.”¹⁷

While the Canadian courts since 2005 have resurrected this statement as authority for the current practice of construing the promise of the patent, this is a *post hoc* interpretation that is not supported by the decision itself.

21. The question of whether the invention was useful was not even at issue in *Consolboard*. The primary issue in both the Court of Appeal and the Supreme Court was whether the patent was invalid for failure to satisfy the disclosure requirement.¹⁸ Utility arose only because the specific disclosure shortcoming alleged was the failure to disclose the utility of the invention. The discussion of utility was by way of brief background – two paragraphs in a 30-page decision – explaining that the Court of Appeal had confused the requirement that the invention be useful (found in section 2 of the *Act*) with the disclosure requirement (then found in section 36(1)) of the *Act*.¹⁹

22. Nor does the Supreme Court’s quotation of *Halsbury’s Laws of England* as a “helpful” source support the view that the Supreme Court intended to affirm or establish the promise of the patent as part Canadian utility law. *Halsbury’s* is an encyclopedia of English law. While the Court in *Consolboard* omitted the footnotes, *Halsbury’s* itself cited three categories of English cases: a line of cases standing for the trite proposition that an invention lacks utility if it is wholly inoperable;²⁰ the old English “false promise” cases;²¹ and a third line of cases rejecting

¹⁷ *Consolboard Inc. v MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504, at 525, 56 C.P.R. (2d) 145 [*Consolboard*] (quoting *Halsbury’s Laws of England*, (3rd ed.), vol. 29, at p. 59, quoted with emphasis in the Dimock Report at ¶ 56) (C-118), rev’g (1979) 41 C.P.R. (2d) 94 (FCA) [*Consolboard FCA*] (C-473).

¹⁸ *Consolboard*, *ibid* at ¶ 514 (C-118); *Consolboard FCA* (C-473).

¹⁹ *Consolboard*, *ibid* at ¶ 527 (C-118).

²⁰ *Manton v Parker*, (1814) Dav Pat Cas 327 (C-443); *Wilson v Union Oil Mills Co., Ltd.*, (1891) 9 R.P.C. 57 (C-444); *Halsbury’s* also cited *Re Smith’s Patent*, (1914) 31 R.P.C. 237 (CA) (C-445), aff’d sub nom. *Natural Colour Kinematograph Co., Ltd. v Bioschemes, Ltd.*, (1915) 32 R.P.C. 256 (HL) (C-446); the Court of Appeal decision deals with sufficiency of disclosure, while the House of Lords decision is the classic English authority on ambiguity as a grounds for invalidity. It is not clear why *Halsbury’s* cited this case on the point at hand.

²¹ *Hatmaker v Joseph Nathan & Co. Ltd.*, (1919) 36 R.P.C. 231 (HL) [*Hatmaker*] (R-179), aff’g (1918) 35 R.P.C. 61 (CA) (C-447); *Re Alsop’s Patent*, (1907) 24 R.P.C. 733 (C-448); and *Morgan v. Seaward*, (1837) 1 Web Pat Cas 187 (C-260).

the notion that an invention had to be better than what went before, as shown by its commercial success.²² The first line of cases dealing with inoperability is unremarkable. In the third line of cases, the statement that a patent will be useful if “it does what the patentee intends” did not imply that the courts must search for and hold the patentee to supposed “promises” derived from the patent, but rather indicated that the invention need only be useful for its intended purpose and need not be “more” useful than what came before. This line of cases set a low bar for utility that is nothing like the promise of the patent.

23. The question, then, is whether the Court, by quoting *Halsbury’s*, intended to incorporate the old English “false promise” cases into Canadian law. The answer is no, for three reasons, any of which would be sufficient on its own.

24. First, when *Consolboard* was decided, the promise analysis had never previously been applied in Canada. It would be quite remarkable for the Supreme Court of Canada to intend to make a major change in the law, on a point that was not at issue, by quoting a few ambiguous words from *Halsbury’s*.

25. Second, the old English “false promise” cases were no longer good law in the UK at the time *Consolboard* was decided. The cited volume (Volume 29 of the 3rd edition of *Halsbury’s*) was published in 1960, but the old English “false promise” law was abolished by the UK *Patents Act, 1977*,²³ and *Consolboard* was decided only in 1981.

26. Third, the basis for the old English “false promise” line of cases is inconsistent with the fundamental nature of the patent grant under the Canadian *Patent Act*. The historical UK “false promise” doctrine was not really a utility doctrine at all. It was based on the fact that in UK law, until 1977, the grant of a patent was a discretionary exercise of the Crown prerogative. This meant that the Crown could in principle refuse a patent even though the invention was patentable. Consequently, if any material representation in the application was false, the courts would hold the patent invalid rather than second-guess the Crown in the exercise of its

²² *Fawcett v Homan*, (1896) 13 R.P.C. 398 (CA) (C-263) and *Lane Fox v Kensington and Knightsbridge Electric Lighting Co.*, [1892] 3 Ch 424, 9 R.P.C. 413 (CA) (C-262).

²³ *Pharmacia Corp. v Merck & Co. Inc.*, [2001] EWCA Civ 1610, ¶ 54 (C-451).

discretion.²⁴ By contrast, in Canadian law, a patent is and always has been a statutory right; the Commissioner of Patents has “no discretion to refuse a patent . . . if the statutory criteria are met.”²⁵ When *Consolboard* was decided, Canada’s *Patent Act* already contained a provision prohibiting the willful making of untrue material misrepresentations in the patent, and the same prohibition exists in section 53 of Canada’s current *Patent Act*.²⁶ This longstanding provision in Canada’s *Patent Act*, which is the closest Canadian parallel to the old English “false promise” doctrine, is not relied on by the courts as authority for Canada’s current promise analysis – and cannot be relied upon for that purpose, given that section 53 requires the impugned statement to be willful, material and untrue. In fact, as noted in my first Report, a challenge to the olanzapine patent on the basis of section 53 of the *Patent Act* failed and the patent was invalidated solely on grounds that it failed to meet Canada’s current utility test.

27. It is absurd to suppose that by quoting an ambiguous sentence from *Halsbury’s Laws of England*, the Court thereby intended to receive into Canadian law all cases cited in the footnotes to *Halsbury’s*, including the old English “false promise cases,” which in any event applied a distinct analysis that did not have its basis in the law of utility, but rather aimed to ensure that a patent that had been conferred at the sovereign’s discretion had not been granted based on material false representations.

28. After quoting from *Halsbury’s*, the Court in *Consolboard* remarked that “Canadian law is to the same effect,” citing the *Metalliflex* decision as an illustration.²⁷ Mr.

²⁴ *Turner v Winter*, (1787) 1 W.P.C. 77, 82 (C-475); *Morgan v Seaward*, (1836) 1 W.P.C. 187, 196 (Exch Ct) (C-260); *Brunton v Hawkes*, (1821) 4 B & Ald 541, 106 ER 1034 at 1039 (KB) (C-476); *Bloxam v Elsee*, (1827) 6 B & C 169, 108 ER 415 (KB) (C-477).

²⁵ *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, ¶ 11 (emphasis in original), Binnie J., (dissenting), accord ¶ 119 (majority) (C-252); *Monsanto*, at 1119-20 (R-23) (quoting *Vanity Fair Silk Mills v Commissioner of Patents*, [1939] S.C.R. 245, 246 (R-149)). The Canadian *Patent Act* was originally based on the U.S. Patent Act, not on English law, and the non-discretionary nature of the grant of a patent in Canadian law follows the U.S. model.

²⁶ The provision was originally introduced with the *Patent Act of 1869*, 32-33 Vict. c. 11, s. 27 in essentially the same terms as it exists today (with only minor grammatical changes to the wording). At the time *Consolboard* was decided the provision was section 55 of the *Patent Act*, R.S.C. 1970, c. P-4.

²⁷ *Metalliflex Ltd. v Rodi & Wienenberger AG*, 19 Fox Pat C 49 (Que QB, Appeal Side), aff’d [1961] S.C.R. 117 [*Metalliflex*] (R-9).

Dimock states that in *Metalliflex*, the Supreme Court of Canada “affirmed that an invention must achieve any result promised by the specification.”²⁸ Contrary to Mr. Dimock’s position, there is no suggestion by the Supreme Court in *Metalliflex* (or at any level of court) that the patentee was being held to a higher standard due to statements in the disclosure that were read to be “promises.” The invention in *Metalliflex* was a watch band. The invention lay in the arrangement of the component parts, but the claim did not specify how the parts were to be held together. The Supreme Court held that it is permissible to refer to the disclosure to “explain the obvious”, namely that the parts should be held together by some means, and consequently the patent was held valid. The word “promise” does not even appear in the Supreme Court decision. While the Court of Appeal decision in *Metalliflex* had made reference to the “promised result” of the invention, the phrase was used only in the anodyne sense to mean the apparent utility of the invention. As noted, the mere use of the word promise does not mean that the court has applied the promise analysis that is applied today, as phrases such as “promised results” are commonly used to mean the apparent or stated utility.

29. Mr. Dimock also emphasizes the following sentence in *Consolboard* in support of his analysis:

If when used in accordance with the directions contained in the specification the promised results are obtained, the invention is useful in the sense in which that term is used in patent law.²⁹

30. *Consolboard* takes this sentence from a 1943 UK decision, *Unifloc Reagents Ltd. v. Newstead Colliery Ltd.*³⁰ Again, in the *Unifloc* case, the use of the words “promised results” did not signal the application of the promise of the patent, or any similar analysis. The utility attack in *Unifloc* was based on the fact that the disclosure of the invention stated that a material that was used to make the invention (a flocculating gel) functioned because it used cellulose membranes, when in fact the membranes were made of starch. The Court held that the misdescription was irrelevant, since it did not affect the utility of the invention: “By following

²⁸ Dimock Report at ¶ 61.

²⁹ *Ibid*, quoted in *Consolboard* (C-118).

³⁰ *Unifloc Reagents, Ltd. v. Newstead Colliery. Ltd.*, (1943) 60 R.P.C. 165, 184 (C-255), quoted in *Consolboard*, at 525 (C-118), quoted with emphasis in the Dimock Report at ¶ 61.

the directions contained in the specification and using the specified materials a gel is produced and that gel is a flocculating gel.”³¹ The point in *Unifloc* is that even erroneous statements in the disclosure as to why the invention works will be considered irrelevant so long as the invention is in fact useful.³² This holding stands in stark contrast to the promise of the patent, which considers statements in the disclosure to be directly relevant to the utility analysis in that such statements become the standard against which utility is assessed.

31. Immediately after quoting *Unifloc*, the Supreme Court in *Consolboard* returned to the central issue in the case, namely the Court of Appeal’s error in interpreting the disclosure requirement, and observed: “I do not read the concluding words of section 36(1) [the disclosure provision] as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful.”³³ The central issue in *Consolboard* was whether the patent was invalid for failing to disclose how the invention (a form of “waferboard”) achieved a stronger board as compared to what had gone before.³⁴ The Court in *Consolboard* had cited *Unifloc* to show that it was established law that statements as to the particular reasons why an invention is useful are irrelevant, so long as the invention is in fact useful. Neither *Metalliflex* nor *Unifloc* applied the promise of the patent, and neither case was cited in *Consolboard* as support for anything similar to the promise analysis.

32. To summarize, far from dealing with the promise of the patent, the disputed issue in *Consolboard* was not even about utility; it was about disclosure. The discussion of utility makes the point that the utility requirement is not onerous, and is satisfied if the invention in fact has utility, regardless of what may or may not be said about it in the disclosure.

b) Other Cases Cited by Mr. Dimock Do Not Apply the Promise of the Patent

³¹ *Unifloc*, *ibid* at 184.

³² The court referred to the issue as “[a]n enormous amount of time . . . wasted.” *Ibid*.

³³ *Consolboard*, at 526 (C-118).

³⁴ See the passages from the Court of Appeal decision quoted in *Consolboard*, at 516 (C-118).

33. Mr. Dimock cites only two cases which he suggests applied the promise of the patent, namely *New Process Screw*³⁵ and *Mobil Oil*.³⁶ He cites two more Canadian cases, *Amfac*³⁷ and *Unilever*,³⁸ as examples of the overbreadth doctrine, which he asserts is similar to the promise of the patent. None of these cases are examples of the promise analysis. Mr. Dimock also cites a UK case, *American Cyanamid*, as an example of what he says is overlap between promised utility and sufficient disclosure.³⁹ *American Cyanamid* applied the UK *Patent Act 1949* and the old English false promise doctrine codified therein and therefore is irrelevant.

Mobil Oil: Utility Is Assessed by Reference to the Claims, Not the Disclosure

34. The Dimock report cites *Mobil Oil* as showing that “*Consolboard* and the promise of the patent were inextricably linked together long before 2005.”⁴⁰ *Mobil Oil* did indeed cite *Consolboard*, but not for the promise doctrine. The passage emphasized by Mr. Dimock is this:

The patent specification promises an oriented polypropylene film substrate having enhanced adhesion to a metallized coating. The evidence indicates that this was indeed achieved.⁴¹

As noted above, it is not unusual for patentees to state the utility of the invention in the disclosure, and in some circumstances, the courts have referred to this stated utility as the “promised” utility (*i.e.* the “promised result”). The passage quoted above simply states that the claimed invention was useful in the sense that it achieved its intended purpose.

³⁵ *New Process Screw Corp. v PL Robertson Mfg Co. Ltd.*, (1961) 39 C.P.R. 31 (Ex Ct) [*New Process Screw*] (R-10).

³⁶ *Mobil Oil Corp. v Hercules Canada Inc.*, (1994) 57 C.P.R. (3d) 488 (FC) [*Mobil Oil*] (R-165); rev'd on other grounds (1995) 63 C.P.R. (3d) 473 (FCA) (R-252), discussed in the Dimock Report at ¶¶ 62-64.

³⁷ *Amfac Foods Inc. v Irving Pulp & Paper, Ltd.*, (1986) 12 C.P.R. (3d) 193 (FCA) [*Amfac*] (R-168), aff'g 80 C.P.R. (2d) 59 (FC), discussed in the Dimock Report at ¶¶ 76-79.

³⁸ *Unilever PLC v Procter & Gamble Inc.*, (1995) 61 C.P.R. (3d) 499 (FCA) (R-172), aff'g (1993), 47 C.P.R. (3d) 479 [*Unilever*].

³⁹ *American Cyanamid Company v Ethicon Ltd.*, [1979] R.P.C. 215 (Ch) (R-173), quoted in the Dimock Report at ¶ 81.

⁴⁰ Dimock Report at ¶ 70.

⁴¹ *Mobil Oil*, at 508 (R-165), quoted with emphasis in the Dimock Report at ¶ 71.

35. If anything, *Mobil Oil* is inconsistent with the promise aspect of the Promise Utility Doctrine. The invention concerned an adhesive. The defendant pointed to data found in the patent disclosure to argue that the claimed invention was for a product that would achieve a specified adhesion strength. The court rejected this view, concluding:

The data presented in the patent does not define the promise of the patent. It is merely provided as an example of the enhanced adhesion which may be achieved using the subject film, as compared with a film of homopolymer polypropylene. If it was intended that the invention relate to a film with at least 250 g/in. bond strength, it would be so claimed.⁴²

Mobil Oil thus stands for the proposition that statements made in the disclosure regarding useful characteristics of the invention – the degree of adhesive strength, in this case – are irrelevant if they are not claimed. *Mobil Oil* rejects the idea that a statement of advantage made in the disclosure ought to be construed as the promised utility. This is inconsistent on its face with the promise of the patent, according to which it is acceptable to hold the patentee to a statement made in the disclosure regardless of what is claimed.

New Process Screw: The Invention As Claimed Was Inoperable

36. *New Process Screw* is not an example of the promise of the patent, because the “promise” (which was not satisfied) was made in the claims, and no higher promise was construed from the disclosure (*i.e.* the “promise” was simply the claimed use of the invention). The claims at issue were to: “A pair of relatively movable screw thread rolling dies capable of only rolling double threads.”⁴³ However, as Mr. Dimock acknowledges, the invention as claimed was wholly incapable of rolling double threaded screws.⁴⁴ In *New Process Screw*, the court did not examine the disclosure to find promises of utility in a manner similar to the promise of the patent, but rather simply found that the claimed invention (a specific technique for producing double threaded screws) did not work. Accordingly, the patent was found to lack utility because the invention as claimed was inoperable.

⁴² *Mobil Oil*, at 513 (emphasis added) (R-165). The Court of Appeal treated the matter as being one of construction and infringement rather than utility.

⁴³ *New Process Screw*, at 42 (emphasis added) (R-10).

⁴⁴ Dimock Report at ¶ 64.

Amfac: The Claims Were Overbroad; Utility Was Not in Issue

37. Another distinct requirement for a patent is that a patentee cannot claim more than she invented. A patent that claims too much is said to be “overbroad.” Mr. Dimock suggests that “[t]he principles underlying promised utility also arise in overbreadth,”⁴⁵ citing the *Amfac* decision as an illustration. Overbreadth as a ground of objection to a patent is quite distinct from utility. A claim is invalid for overbreadth if it encompasses more subject matter than what has actually been invented and disclosed, even though the claimed subject matter might be very useful.⁴⁶

38. *Amfac* is an overbreadth case that similarly has nothing to do with “promises” of utility, or utility by any standard. The *Amfac* decision, at both levels of court, is replete with references to overbreadth, and it is a leading decision on that doctrine,⁴⁷ but it has never been judicially cited as an example of the promise of the patent. The invention at issue was a machine for slicing potatoes into french fries by using high-pressure water to force the potato through a pipe and through cutter blades fixed inside the pipe. The machine sliced the centre of the potato into long fries, leaving outer slabs that were then diverted to other uses. Claim 16 covered the general machine which used water pressure to slice potatoes, while Claims 17 and 18 claimed the further refinement of diverting the outside slabs to other uses. The court held that what the inventor had really invented was only the refinement of diverting the outer slabs. Claim 16 was consequently held to be invalid for overbreadth: the claim was to a hydraulic potato slicing machine, while the true invention was only a refinement to such a machine. On its face, and in fact, the patent was held to be invalid purely for overbreadth. Utility was never in issue.

⁴⁵ Dimock Report at ¶ 64.

⁴⁶ A famous example is Morse’s eighth claim in his telegraph patent, which claimed any method for using electromagnetism for communication at a distance, when what Morse had invented was only one such method, the telegraph. The patent was not invalid for want of utility (the telegraph was undoubtedly useful, as were any other methods for using electromagnetism for communication at a distance), but the impugned claim was overbroad because it encompassed other methods for using electromagnetism for communication at a distance, even though Morse had invented only the one method. *O’Reilly v Morse*, 56 U.S. 62, 112-13 (1854) (C-454).

⁴⁷ See e.g. *Pfizer Canada Inc. v Pharmascience Inc.*, 2013 FC 120, ¶¶ 83-86 (C-180); *Bristol-Myers Squibb Canada Co. v Mylan Pharmaceuticals ULC*, 2012 FC 1142, ¶ 71 (C-455); *MK Plastics Corp. v Plasticair Inc.*, 2007 FC 574, ¶ 121 (C-456); *Visx Inc. v Nidek Co.*, (1999) 3 C.P.R. (4th) 417, ¶ 145 (FC) (C-457); *Apotex Inc. v Wellcome Foundation Ltd.*, (1998) 79 C.P.R. (3d) 193, ¶ 275 (FCTD) (C-116); *Whirlpool Corp. v Camco Inc.*, (1997) 76 C.P.R. (3d) 150, ¶ 63 (FC) (C-254). This list is not exhaustive.

Unilever: Overbreadth Is To Be Assessed by Reference to the Claimed Invention

39. Mr. Dimock also cites the *Unilever* case as illustrating a similarity between overbreadth and the promise of the patent. This is incorrect. The defendants argued that the patent should be held invalid if it failed to satisfy an objective that was stated in the disclosure but not in the claims.⁴⁸ But this argument, which resembles the promise analysis, was rejected by the court. Mr. Dimock asserts that this argument “failed on the facts”,⁴⁹ implying that the principle supports the promise utility doctrine. That is not correct. The defendants argued the term “distributing agent” in the claim meant a substance that would reduce staining.⁵⁰ The defendants’ argument failed because the trial judge construed that term to mean a substance that helps spread the fabric softener. Given this claim construction, it did not matter what the patent might have “promised” regarding stain reduction: the argument “falls to the ground”, as the Court of Appeal put it.⁵¹ That is, the court in *Unilever* refused to accept the defendants’ assertion that statements in the disclosure could amount to a “promise”, on the basis that utility was to be assessed by reference to the claimed invention. By contrast, under the promise analysis that is applied today, the claims can be abundantly clear, but if the disclosure is construed to promise a particular result, that result must be met. As with *Mobil Oil*, far from being an illustration of the promise analysis, *Unilever* is, if anything, inconsistent with it, because it makes clear that statements made in the disclosure alone are irrelevant to the utility analysis.

Commentators

40. Mr. Dimock cites three commentators as supporting the view that the promise of the patent was part of Canadian law.⁵² However, the only law cited by these commentators is the old English “false promise” doctrine, which as noted, did not form part of Canadian law and

⁴⁸ See the passage from *Unilever*, at 511-12 (R-172), quoted in the Dimock Report at ¶ 80, emphasis added by Mr. Dimock.

⁴⁹ Dimock Report ¶ 80.

⁵⁰ *Unilever*, at 510-11 (R-172).

⁵¹ *Unilever*, at 508 (R-172).

⁵² Dimock Report at ¶¶ 66, 62 and 65, respectively, citing Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969), at 150-153 [Fox] (R-163); Mr. Henderson’s editorial note to *New Process Screw*, at 33-34 (R-162); and Donald Hill, “Claim Inutility” (1960) 35 C.P.R. 185, at 188 (R-160).

finds its closest parallel in section 53 of Canada's *Patent Act*.⁵³ It is the Canadian courts that make Canadian law, and the fact that some commentators cited these English cases does not make them part of Canadian law.

(iii) There Is No Valid Policy Basis for Construing a Promise of the Patent

41. In his report, Mr. Dimock maintains that since patents have always been “construed in an informed manner by a person skilled in the art,” that implies that the courts have always undertaken to construe the “promise of the patent.”⁵⁴ This is incorrect. What is true is that the courts consider the disclosure, when necessary, to construe the claims and to assess the sufficiency of disclosure in view of what is claimed.⁵⁵

42. While this new practice of construing the promised utility is presented as an objective exercise,⁵⁶ in practice it is subjective and arbitrary. Construing the promise turns on fine grammatical parsing and hair-splitting with regards to statements in the specification that are often only tangentially related to the claimed subject matter. This point was illustrated in my first Report, in the discussion of the *Anastrozole* decision. In that case, the construction of the “promise of the patent” consumed sixty-two paragraphs of a 233-paragraph decision. While there

⁵³ In his discussion of “Promised Results”, at 152-53 (R-163), Fox discusses at length the leading UK cases which established the doctrine, namely *Hatmaker* (C-447), and *Re Alsop's Patent* (C-448), as well as the leading UK case restricting it, *Raleigh Cycle Co. Ltd. v H Miller & Co. Ltd.*, (1948) 65 R.P.C. 141, 1 All ER 308 (HL) (C-467). The only Canadian cases he cites anywhere in this section of his treatise are *Rowell v. S. & S. Industries Inc.*, (1964) 28 Fox Pat C 79, 44 C.P.R. 260, aff'd 33 Fox Pat C 56, [1966] S.C.R. 419 (C-466) (cited by Fox, *ibid* at 152, fn 42) and *Société des Usines Chimiques Rhone-Poulenc v Jules R Gilbert Ltd.*, (1967) 35 Fox Pat C 174, 55 C.P.R. 207, aff'd [1968] S.C.R. 950, 55 C.P.R. 207 (R-186) (cited by Fox, at 153, fn 43 (R-163)). In *Rowell*, the false “promise”, that “torsional twisting” would be avoided, was found in the claims (44 C.P.R. at 270) and consequently the patent was explicitly held invalid for insufficient disclosure (44 C.P.R. at 286), which is to say that the disclosure was not adequate to tell a skilled person how to make the claimed invention. In *Rhone-Poulenc v Jules R Gilbert*, the claim in question was held invalid for inoperable species, and there is no suggestion that the species in question were good for anything at all. Mr. Henderson cites *Alsop's Patent* (C-448) and *Hatmaker* (C-447), and Mr. Hill cites *Hatmaker* and *Kraft Cheese v McAnulty*, (1931) 48 R.P.C. 535 (JCPC) (C-469), a decision for the Judicial Committee of the Privy Council on appeal out of Australia.

⁵⁴ Dimock Report at ¶ 88.

⁵⁵ *Burton Parsons Chemicals, Inc. v Hewlett-Packard (Canada) Ltd.*, [1976] 1 S.C.R. 555 (C-201) and *Western Electric Co. v Baldwin International Radio of Canada*, [1934] S.C.R. 570, 572 (R-178) (sufficiency), and *Whirlpool*, at ¶ 48 (C-256) (claim construction).

⁵⁶ *Apotex Inc. v Pfizer Canada Inc.*, 2011 FCA 236, ¶ 17 (R-177); *Plavix*, at ¶ 33 (C-47).

was often a similarly extensive discussion of construction of the claims in prior cases, there is no example of a similarly extensive exercise construing the promised utility in any case prior to 2005.⁵⁷

43. Mr. Dimock advances several policy rationales for this searching probe for the promise of the patent, none of which withstands scrutiny. First, Mr. Dimock asserts that “[i]f a patentee is not held accountable for their promises, the public is subject to the negative effects of the patent in exchange for less than what was agreed to through the patent bargain at the outset.”⁵⁸ This is incorrect as a matter of law. The patentee fulfils the “patent bargain” by disclosing to the world a new, useful and non-obvious invention. Even today, the courts acknowledge that a “mere scintilla” of utility fulfils this bargain, unless a so-called “promise” is made. While it is reasonable to say that patentees should not be able to obtain a patent on the basis of lies or misrepresentations, that is not the purpose of the promise of the patent. As discussed, misrepresentations in the patent are policed by section 53(1) of the Canadian *Patent Act*, which provides that a patent is invalid if any material allegation is untrue and wilfully misleading. As discussed, misrepresentations in the patent are policed by section 53(1) of the Canadian *Patent Act*, which provides that a patent is invalid if any material allegation is untrue and wilfully misleading.

44. Mr. Dimock’s assertion furthermore ignores that the “promise of the patent” is only one aspect of Canada’s current utility requirement, the Promise Utility Doctrine. Another aspect is that any so-called promises of the patent must be demonstrated or soundly predicted by evidence available at the date the patent was filed, and in the case of sound prediction, disclosed within the patent itself. Mr. Dimock’s assertion that Canada’s current utility requirement exists to hold patentees “accountable” for their promises ignores that, due to this evidentiary rule, a patent may be held invalid for failure to meet Canada’s utility requirement even though the invention in fact fulfilled each and every one of its so-called promises.

⁵⁷ Mr. Dimock cited some commentators discussing the need to construe the specification, and one case which briefly identified the utility with reference to the disclosure (Dimock Report at ¶¶ 68-71), but he provides no examples of cases similar to *Anastrazole*, with an extensive discussion of the construction of the promised utility.

⁵⁸ Dimock Report at ¶ 72.

45. Mr. Dimock also claims that the quality of the patent disclosure “is enhanced by a rule that holds patentees to the promises that they make.”⁵⁹ On the contrary, the promise of the patent is inimical to the quality of the patent disclosure. As Mr. Dimock notes, one aim of the disclosure is to enable the public to build upon the invention in new lines of research, and to practice the invention upon expiry of the patent.⁶⁰ To this end, there should be a fulsome disclosure of all the patentee knows; however, the promise of the patent runs counter to this aim by encouraging a patentee to be restrictive in its disclosure for fear that statements of advantage or potential might be misconstrued as a promise, thus risking invalidation.

46. Third, Mr. Dimock suggests that the promise of the patent is “particularly germane” in the case of new use and selection patents.⁶¹ This is an *ad hoc* justification tailored to the patents at issue. His suggestion that the promise of the patent is particularly applicable to certain types of patents is not a valid justification, not least because the promise analysis has been applied to every type of pharmaceutical patent, including those that claim previously unknown compounds.⁶²

47. Where the invention is a “new use”, the patent bargain is met simply by the disclosure of the new use. Prior to disclosure of the atomoxetine (Strattera) patent, it was not known that atomoxetine was useful to treat ADHD. Afterwards it was known. The patent was held to be invalid only because the patent was held to a higher standard of utility that was based on an implied “promise” of clinical efficacy in the longer term.

48. Where the invention is a selection from a genus, it is true that the selection must have special advantages as compared with the genus,⁶³ but this is in order to satisfy the non-

⁵⁹ Dimock Report at ¶ 74.

⁶⁰ Dimock Report at ¶ 74.

⁶¹ Dimock Report at ¶ 73.

⁶² *Pfizer Canada Inc. v Apotex Inc.*, 2005 FC 1205 (C-250), rev’d on other grounds 2007 FCA 209, ¶ 153 (quinapril) (C-215); *Aventis Pharma Inc. v Apotex Inc.*, 2005 FC 1283, 43 C.P.R. (4th) 161 (ramipril) (C-214), aff’d 2006 FCA 64, 46 C.P.R. (4th) 401; *Laboratoires Servier v Apotex Inc.*, 2008 FC 825, aff’d 2009 FCA 222 (perindopril) (C-474); *GlaxoSmithKline Inc. v Pharmascience Inc.*, 2011 FC 239 (rosiglitazone) (C-249); *Astrazeneca Canada Inc. v Mylan Pharmaceuticals ULC*, 2011 FC 1023, 96 C.P.R. (4th) 159 (anastrozole) (C-237), aff’d 2012 FCA 109 (C-236); *Novartis Pharmaceuticals Canada Inc. v Teva Canada Ltd.*, 2015 FC 770 (deferasirox) (C-471).

⁶³ *Apotex Inc. v Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, ¶ 10, [2008] 3 S.C.R. 265 [*Sanofi*] (C-196).

obviousness requirement.⁶⁴ To view those stated advantages as also being the “promised utility” is at best redundant with the non-obviousness requirement. At worst, the courts have found that the patentee “promised” even more than would be required to show that the invention is non-obvious, and have invalidated the patent for failure to meet this “promised utility”, even though the invention is useful and non-obvious.

49. This is exactly the type of additional burden that was imposed in the *Olanzapine* (Zyprexa) litigation at issue in these proceedings. The patent was held to have been non-obvious.⁶⁵ Under the traditional approach, utility was never an issue in respect of selection patents, on the sound principle that all the compounds within a valid genus patent must have had patentable utility, and so any compound selected from that genus would also have utility.⁶⁶ But because of the promise of the patent analysis, all the statements in the disclosure were treated as promises. The court therefore held that to satisfy the utility requirement, the patentee had to establish (based only on evidence available at the time of filing): “that olanzapine is substantially better (‘marked superiority’) in the clinical treatment of schizophrenia (and related conditions) than other known antipsychotics, with a better side-effects profile, and a high level of activity at low doses.”⁶⁷

50. Mr. Dimock asserts that a selection patent “must assert an enhanced utility vis-à-vis the genus.”⁶⁸ That is true today, but only because of the recent changes in Canada’s utility

⁶⁴ See *Sanofi*, *ibid* at ¶¶ 79- 93 (C-196), the leading Canadian case on selection patents, discussing the validity of the selection entirely in terms of non-obviousness. The generic challenger did not attack the utility of the patent at all. If, as asserted by Mr. Dimock, it has always been well-established that the validity of a selection patent turns on the utility requirement, the generic company surely would have raised this issue. The reason for requiring special advantages is based on the non-obviousness requirement, because given that it is already known that all members of the genus have certain properties, there will be no “inventive step” in selecting a species from that genus unless the species possesses unexpected properties or surprisingly better activity over the class of compounds in the genus.

⁶⁵ *Olanzapine (No. 1)*, at ¶ 64 (C-46).

⁶⁶ As noted by Maugham J. in *In re I. G. Farbenindustrie A. G.’s Patents*, (1930) 47 R.P.C. 289, 309 (Ch) (R-12), which the Supreme Court of Canada in *Sanofi*, at ¶ 9 (C-196) referred to as the “*locus classicus*” describing selection patents, utility is irrelevant to selection patents: “Strictly speaking, utility has no application to a selection Patent since you start with the assumption that the combinations from which the selection is made do work.”

⁶⁷ *Eli Lilly Canada Inc. v Novopharm Ltd.*, 2011 FC 1288, ¶ 124, 100 C.P.R. (4th) 269 (C-146), *aff’d* 2012 FCA 232 [*Olanzapine (No. 2)*] (C-147).

⁶⁸ Dimock Report at ¶ 167.

requirement after the adoption of the Promise Utility Doctrine. Under the prior law, the olanzapine (Zyprexa) patent would necessarily have been considered to have utility, precisely because it was a selection patent; a selection from a genus of useful compounds must itself be useful. The requirement that a selection patent must have an elevated utility is a consequence of the promise of the patent, not a cause. While the olanzapine patent was a selection patent, it was not invalid for that reason; it was invalid only due to the additional requirements for utility imposed by the Promise Utility Doctrine.

B. Post-filing Evidence

51. As discussed in my initial Report,⁶⁹ the heightened standard for utility imposed by the promise of the patent may lead to heightened evidentiary scrutiny by judges, yet since the 2002 decision of the Supreme Court in Canada in *AZT*, post-filing evidence is inadmissible to establish utility. Mr. Dimock states that “we appear to be in agreement” that “[i]n Canada, the utility of the invention must either be demonstrated or soundly predicted as of the Canadian filing date of the patent application.”⁷⁰ I would not put it that way, especially prior to the *AZT* decision.⁷¹ To repeat what was said in my first Report, “[i]n Canadian patent law, utility must be assessed with respect to the invention as disclosed and claimed at the time of filing.”⁷² This means that utility of the invention cannot be established by showing the utility of a different version of the claimed invention: “it is the precise form of the alleged invention claimed in the patent in suit which is to be considered.”⁷³ To give an example, if the invention is an airplane, and the version of the airplane disclosed and claimed in the patent does not work because the wings are the wrong shape, evidence that the inventor later constructed and flew an improved

⁶⁹ Siebrasse First Report at ¶¶ 106-108.

⁷⁰ Dimock Report at ¶ 92.

⁷¹ *AZT*, at ¶ 37 (C-213).

⁷² Siebrasse First Report at ¶ 29.

⁷³ Editor’s Annotation to the Exchequer Court decision in *Wandscheer v Sicard*, (1944) 4 Fox Pat Case 43 at 44 (C-259); and see the Annotation generally for extensive cases references to the same effect. In his report, at ¶ 93, fn 106, Mr. Dimock cites *Fox*, at 160-61 (R-163) for the proposition that “when Canada had a first-to-invent patent system, rather than a first to file system, the material date for assessing utility was the date of invention, rather than the date of filing.” This is misleading. In fact, the passage states the proposition, which is still good law today, that an inventor cannot be allowed to say “it is true my invention will not so work, but it will work when altered by a subsequently discovered material or device.”

version of the airplane would not be admissible to support the utility of the invention as of the filing date.⁷⁴ However, prior to *AZT*, evidence that an airplane of the same design as that disclosed and claimed in the patent has been flown *was* admissible to show that the invention had the requisite utility on the filing date.

52. Since the Supreme Court of Canada’s 2002 decision in *AZT*, it is clear that such post-filing evidence – the fact that the airplane of the disclosed design later had been flown successfully – would not be admissible as evidence that the airplane of the disclosed design was capable of flight when the patent was filed. The question is whether the Supreme Court decision in *AZT* changed the law, or affirmed it. As another example, consider a patent that claims a chemical compound and discloses that the compound is useful for treating diabetes, and that compound is in fact useful for treating diabetes. Is the fact that the compound is widely and successfully used to treat diabetes currently, at the time of trial, admissible to prove that it had patentable utility for treating diabetes at the time of filing?

53. Prior to the 2002 *AZT* ruling, the Canadian courts would allow evidence that an invention is commercially successful to establish that it had utility at the time of filing. Since the 2002 *AZT* decision, such post-filing evidence has not been admissible. Mr. Dimock’s assertion that the 2002 *AZT* decision affirmed the law (versus changing it) is unsupported by the jurisprudence.

(i) No Case Law Prior to *AZT* Excludes Post-filing Evidence

54. Mr. Dimock asserts that “it has long been understood in Canadian patent law that post-filing evidence is not available to prove that an inventor had made the invention by the filing date of the patent application (including satisfaction of the utility requirement).”⁷⁵ However, the sole case cited by Mr. Dimock for this proposition is *AZT* itself – the very case in which the Supreme Court of Canada, in overruling the Federal Court of Appeal, changed the law on this point. In *AZT* the Federal Court of Appeal, affirming the trial judge, held that utility can be proven using any evidence that is available when the patent is attacked. The Supreme Court of

⁷⁴ See e.g. *The King v Meyers Canadian Aircraft Co. Ltd.*, [1931] Ex CR 146 (C-460).

⁷⁵ Dimock Report at ¶ 102

Canada reversed on this point, holding that only evidence available as of the priority date, or, at the latest, the filing date, is admissible to establish utility.⁷⁶

55. Contrary to his assertion, Mr. Dimock does not provide even one example of a case prior to AZT in which post-filing evidence of utility was excluded. The sole pre-AZT case cited by Mr. Dimock as relevant to the question is *Ciba-Geigy*, a case in which post-filing evidence was admitted to establish utility, as Mr. Dimock acknowledges.⁷⁷ If the rule in *AZT* were long-established, as Mr. Dimock asserts, then we should expect to find at least one case in the previous 100 years of patent litigation in which the rule was applied. Mr. Dimock does not cite any, and to my knowledge there are no such cases.

(ii) Numerous Pre-AZT Decisions Admitted Post Filing Evidence to Support Utility at the Date of Filing

56. In my Report I cited numerous cases in which the courts had considered pre-filing evidence in assessing utility.⁷⁸ Mr. Dimock attempts to dismiss these cases on the basis of a distinction between “utility-in-fact (operability)” and whether utility was demonstrated or soundly predicted at the time of filing.⁷⁹ As a preliminary point, “inoperability” is not an independent ground of invalidity under the *Patent Act*. As Mr. Dimock emphasizes, there is only one reference to utility in the *Patent Act*.⁸⁰ To say an invention is inoperable is merely to say that it lacks utility.⁸¹ With that said, I understand Mr. Dimock to be saying that under both current

⁷⁶ Siebrasse First Report at ¶ 85.

⁷⁷ Dimock Report at ¶ 106.

⁷⁸ Siebrasse First Report at ¶ 30.

⁷⁹ Dimock Report at ¶ 105. Mr. Dimock, *ibid*, also suggests that there was a separate question as to whether the invention was “reduced to a definite and practical shape.” That inquiry normally arose in the context of dispute as to which of two parties was the first to invent under the old “first-to-invent” system. The ultimate question in that context was not “does your invention work?” but “were you the first to have a working invention?” That question was normally resolved by evidence that was contemporaneous with the reduction to practice (*e.g.* laboratory notebooks), however, that in no way establishes that post-filing evidence of utility was inadmissible.

⁸⁰ Dimock Report at ¶ 55.

⁸¹ *Northern Electric Co. v. Brown's Theatres Ltd.*, (1939) 1 C.P.R. 180 (Ex Ct) at 202 (C-472), *aff'd* (1941), 1 C.P.R. 203 (SCC). Sometimes an invention is said to be “inoperable” when it would not work as claimed, regardless whether what is claimed it itself useful. For example, even though a perpetual motion machine would be extremely useful if one could be built, a claim to a perpetual motion machine will be said to lack utility as being inoperable because the specification will not actually allow a perpetual motion machine to build built: *Otta v Canada (Patent*

and prior Canadian law, post-filing evidence was admissible to show lack of utility (which he refers to as inoperability), and I agree.⁸² I also take him to be saying that under current law post-filing evidence is not admissible to show that the invention had utility as of the date of filing. Again, I agree. But I also understand him to be saying that that under prior law post-filing evidence was not admissible to show that the invention had utility as of the date of filing. On that point, I disagree.

57. Mr. Dimock states: “In all but one of the cases cited by Professor Siebrasse, such ‘post-filing’ evidence was provided to rebut allegations of invalidity, in that the invention was obvious or it was not operable.”⁸³ By this, I understand him to be saying that the defendant had adduced evidence of lack of utility (*i.e.* inoperability at the date of challenge) in some respect and that post-filing evidence of utility was admitted solely in rebuttal. Mr. Dimock’s view is not borne out by the cases.

58. Firstly, there are a number of cases which do specify the nature of the utility attack and which are contrary to Mr. Dimock’s position.⁸⁴ For example, in *Omark v Gouger* the defendant first attacked the patent on the basis of “inoperability.” After dismissing that attack, the court dealt with “utility” as a separate ground of attack, and dismissed the utility attack based on post-filing evidence, namely commercial success.⁸⁵ In *Reliable Plastics*, the court noted that apart from some attacks on the ground that the devices “would not work,” “utility” was proved

Commissioner), (1979) 51 C.P.R. (2d) 134, 138 (PAB) (C-211), *aff’d* 51 C.P.R. (2d) 139 (FCA); and see *Wellcome Foundation Ltd. v. Apotex Inc.*, (1991) 39 C.P.R. (3d) 289, 338 (FCTD) (C-41); *Omark Industries (1960) Ltd. v Gouger Saw Chain Co.*, 45 C.P.R. 169, 223 (Ex Ct) (C-224). In other cases, inoperability is used essentially as a synonym for lack of utility, particularly in extreme cases where the invention is entirely useless.

⁸² Siebrasse First Report at ¶ 55.

⁸³ Dimock Report at ¶ 105.

⁸⁴ There are also several cases which did involve an attack based on inoperability of specific embodiments: *Jamb Sets Ltd. v Carlton*, [1964] Ex CR 377 (C-222); *Energy Absorption Systems Inc. v Y Boissoneault & Fils Inc.*, (1990) 30 C.P.R. (3d) 420, at 459 (FCTD) (C-227); *Bayer AG v Apotex Inc.*, (1995) 60 C.P.R. (3d) 58, at 90 (OCJ - GD) (C-40); *Risi Stone Ltd. v Groupe Permacon Inc.*, (1995) 65 C.P.R. (3d) 2, at 21 (FCTD) (C-229); *Almecon Industries Ltd. v Anchoortek Ltd.*, (2001) 17 C.P.R. (4th) 74, at 99 (FCTD) (C-230); and *Illinois Tool Works Inc. v Cobra Fixations Cie / Cobra Anchors Co.*, (2002) 20 C.P.R. (4th) 402, at 432 (FCTD) (C-231). These are consistent with both Mr. Dimock’s view and my own.

⁸⁵ *Omark*, at 220-23 (C-224).

“beyond dispute” by post-filing evidence.⁸⁶ If Mr. Dimock were right, then in both of these cases the post-filing evidence would only have been admissible in respect of the “inoperability” attack, not the separate utility attack. In *Boehringer v Bell-Craig*, the court held a claim to a broad class of compounds invalid for lack of sound prediction, but the court stated that it would have been willing to admit post-filing evidence to establish utility.⁸⁷ In *Cochlear Corp. v Cosem Neurostim* the court stated that “[t]he utility of a patent may be proven by the reception received from the public, *i.e.* its commercial success,” and continued in the very next sentence to state expressly that utility “is . . . to be judged at the date of the making of the invention, in light of the knowledge existing at that time.”⁸⁸ On the facts, post-filing evidence was admitted to establish utility.⁸⁹ The same was true in the pharmaceutical context; in *Hoechst v Gilbert* the court accepted evidence of actual use of tolbutamide as establishing its utility in treating diabetes.⁹⁰

59. Secondly, many of the cases do not detail the basis for the allegation of lack of utility, but state only that lack of utility was alleged and defeated by post-filing evidence, typically commercial success.⁹¹ There is no suggestion in these cases that the defendant had

⁸⁶ *Reliable Plastics Ltd. v Louis Marx & Co.*, (1958) 29 C.P.R. 113, 126 (C-218). The argument that the devices would not work when implemented using some plastics falling within the claims: *ibid* at 128-29. This was clearly an attack based on inoperability as of the time of trial, and the post-filing evidence was *not* adduced in rebutting this argument, which failed instead as a matter of claim construction.

⁸⁷ *CH Boehringer Sohn v Bell-Craig Ltd.*, [1962] Ex CR 201, 245 (C-221), *aff'd* [1963] S.C.R. 410, 41 C.P.R. 1 (SCC).

⁸⁸ *Cochlear Corp. v Cosem Neurostim Ltée*, (1995) 64 C.P.R. (3d) 10, 35 (FCTD) (C-228).

⁸⁹ *Ibid* at 35, referring to commercial success; the testimony of an individual who used the device was also admitted to establish utility: *ibid* at 13.

⁹⁰ *Hoechst Pharmaceuticals of Canada Ltd. v Gilbert & Co.*, [1965] 1 ExCR 710, at 714, 28 Fox Pat. C. 120, 50 C.P.R. 26, *aff'd* [1966] S.C.R. 189, 191, 50 C.P.R. 26 (C-301). The claim at issue was held to be invalid because the useful compound was claimed as a member of a class and utility had not been established for all members of the class, but the point remains that post-filing evidence was used to establish the utility of a compound for treatment of a disease.

⁹¹ See *Wright and Corson v Brake Service Ltd.*, [1925] Ex CR 127, at 131, *aff'd* [1926] S.C.R. 434 (C-300); *Prentice v Dominion Rubber Co.*, [1928] Ex CR 196, at 199 (Ex Ct) (C-207); *Unipak Cartons Ltd. v Crown Zellerbach Canada Ltd.*, (1960) 33 C.P.R. 1, at 9-10, 38-39, [1956-1960] Ex CR 396 (C-219); *Ernest Scragg & Sons Ltd. v Leeson Corp.*, (1964) 45 PR 1, at 89 (Ex Ct) (C-223); *McPhar Engineering Co. of Canada v Sharpe Instruments Ltd.*, (1960) 35 C.P.R. 105, at 128, 140 (C-220). In *Gorse v Upwardor Corp.*, (1989) 25 C.P.R. (3d) 166, 183 (FCTD) (C-226) and *Canadian Patent Scaffolding Co. v Delzotto Enterprises Ltd.*, (1978) 42 C.P.R. (2d) 7, at 21 (FCTD) (C-225), *aff'd* 47 C.P.R. (2d) 77, 82 (FCA), the utility attack is described, but it is unclear whether the argument was that the invention was not useful as the date of filing or as of the date of trial. In *Asten-Hill Ltd. v*

adduced any evidence of lack of utility at the time of trial. Mr. Dimock apparently infers from this silence that the attack must have been based on evidence of lack of utility at the time of trial. The proper inference is to the contrary. The reason that the precise basis for the allegation was not specified is that it did not matter; prior to *AZT*, post-filing evidence was admissible whether the attack was based on evidence of lack of utility at the time of trial or lack of utility at the date of filing, and the courts did not distinguish between the two, on the basis that, if the invention has utility today, it must have been useful when filed. If Mr. Dimock were correct in saying that under prior law, post-filing evidence was admissible for some utility attacks but not others, we would expect the nature of the attack and the relevant date to be specified, as is routine today.⁹²

60. Today it is much more common for a defendant to allege that the patentee had not made an invention at the time of filing (to use Mr. Dimock's terminology), because the patentee is then restricted to relying on pre-filing evidence. Allegations that the commercially valuable product is not useful at the date of trial (*i.e.* "inoperable" at the date of challenge) are essentially unheard of. Such allegations are nearly impossible to establish because the patentee is entitled to rebut the allegation with evidence that the product works and is commercially successful.⁹³ If indeed it were always true that post-filing evidence is not admissible to establish that the invention was useful at the time of filing, then we should expect such attacks to always have been common, just as they are today. There are, however, no decisions prior to 2002 that state or even suggest that a patent could be held invalid on the basis that only pre-filing evidence of utility was admissible, or that hold that the patent failed because such evidence failed to show utility at the date of filing.

Ayers Ltd., [1939] 2 DLR 234, 246 (Ex Ct) (C-208) and *Langlois v Roy*, [1941] Ex CR 197, 203, 1 C.P.R. 63, 66-67 (C-217), lack of utility was not alleged, and the court simply noted that utility can be established by commercial success. In these cases the point remains that if the admissibility of such evidence turned on the nature of the utility attack, the court would have said so.

⁹² See e.g. *Teva Canada Ltd. v. Novartis AG*, 2013 FC 141, ¶ 161 (C-470); *Aventis Pharma Inc. v Apotex Inc.*, 2005 FC 1283, 43 C.P.R. (4th) 161, ¶¶ 29-30 (C-209), aff'd 2006 FCA 64, 46 C.P.R. (4th) 401 [*Aventis*] ¶¶ 91-96 (C-214); *Pfizer Canada Inc. v Apotex Inc.*, 2007 FCA 209 at ¶ 153 (C-215); *Eli Lilly Canada Inc. v Apotex Inc.*, 2008 FC 142, ¶ 162, 63 C.P.R. (4th) 406 (C-115), aff'd 2009 FCA 97, 78 C.P.R. (4th) 388.

⁹³ Lack of utility at the time of trial is typically only alleged when the claim is broad and some species within the claim are not useful.

61. As I noted in my first report, prior to *AZT* the courts did not even distinguish between pre- and post-filing evidence because the distinction was simply irrelevant.⁹⁴ In contrast, under current law the courts specify explicitly whether evidence is pre- or post-filing, because only the former is admissible.

(iii) Uncertainty Regarding Precise Contours of *AZT* Decision Shows that the Rule Excluding Post Filing Evidence Originates with That Decision

62. A further indication that the rule against post-filing evidence is new is the uncertainty subsequent to *AZT* as to whether the crucial cut-off date was the patent's priority date or its filing date, a point on which the *AZT* decision was ambiguous. Subsequent cases in the Federal Courts examined the decision in *AZT* and concluded that the correct date is the Canadian filing date.⁹⁵ If the rule against post-filing evidence were long-established, as Mr. Dimock asserts, then there would have been no confusion as to the cut-off date in the first place, and any possible ambiguity would have been resolved by looking to earlier case law.

C. Disclosure of Basis for Sound Prediction

63. It is uncontroversial and long-established that the requirement for sufficient disclosure requires the patentee to set out in the patent a description of how to make and use the invention.⁹⁶ It is also true that, if it would not otherwise be apparent to the reader of the patent, the utility of an invention must be disclosed in the patent itself.⁹⁷ However, in current Canadian law, the courts have imposed an additional, distinct disclosure obligation as part of the utility requirement. Specifically, when utility is established on the basis of sound prediction, the factual basis for that prediction – that is, the evidence on which a sound prediction of utility is based –

⁹⁴ Siebrasse First Report at ¶ 30, fn 39.

⁹⁵ The leading case on this point is *Aventis Pharma Inc. v Apotex Inc.*, 2005 FC 1283, 43 C.P.R. (4th) 161, ¶¶ 91-96, aff'd 2006 FCA 64, 46 C.P.R. (4th) 401, ¶ 30 [*Aventis*] (C-209).

⁹⁶ Siebrasse First Report at ¶ 38; Dimock Report at ¶ 114.

⁹⁷ Dimock Report at ¶¶ 117-23. Mr. Dimock, at ¶ 117, notes that in some instances disclosure of the utility of an invention is required. This is true but irrelevant, as this requirement is uncontroversial and not in issue. It is one thing to identify the utility of a compound (*e.g.* "This compound cures the common cold") and quite another to include data to support this utility in the patent (*e.g.* by disclosing a clinical study that indicates that indicates the compound was administered to 47 human subjects and 68% of the study group reported reduced symptoms).

must be disclosed in the patent itself. The Canadian courts refer to this as an “additional,” “heightened,” or “enhanced” disclosure requirement applicable only when utility is based on sound prediction.⁹⁸ Mr. Dimock’s assertion that this heightened disclosure requirement is not new is unsupported by the materials he cites and is contradicted by the treatment of this new requirement in recent case law.

(i) The Traditional Requirement for Sufficient Disclosure Is Irrelevant to the Issue

64. In his report, Mr. Dimock states that “Disclosure lies at the ‘very heart of the patent bargain,⁹⁹ and that “proper disclosure requires that “[t]he skilled person must be able to produce the invention having only the instructions contained in the disclosure and the common general knowledge in the art.”¹⁰⁰ While this is an accurate characterization of the uncontroversial requirement for sufficient disclosure, it is irrelevant to the question of whether, as part of Canada’s law of utility, the courts have imposed a new and distinct requirement to include proof or evidence of a sound prediction of utility within the patent itself. The traditional requirement for sufficient disclosure does not require disclosure of the evidence of utility, any more than it requires disclosure of evidence establishing novelty or non-obviousness. If a patentee invents a new compound that cures the common cold, and discloses how to make that compound, and how much should be administered, and the compound does cure the common cold, then the requirement for sufficient disclosure is met. That is true whether or not data predicting that the compound will cure the common cold is found in the patent itself – the distinct requirement that is at issue here.

⁹⁸ See sources cited in the Siebrasse First Report at ¶ 66.

⁹⁹ Dimock Report at ¶ 114.

¹⁰⁰ Dimock Report at ¶ 115; see to the same effect Siebrasse First Report at ¶ 38.

(ii) **The Sources Cited by Mr. Dimock Do Not Support the View that the Heightened Disclosure Requirement for Sound Prediction Is Long Established**

65. Mr. Dimock cites a patent tutorial (*Hayhurst*) that in turn cites decisions in *Olin Matheson*, *Monsanto*, and *AZT*. None of these sources support his contention that the additional disclosure requirement is long-established as part of Canada's law of utility.

a) ***Hayhurst / Olin Matheson***

66. In the patent tutorial relied on by Mr. Dimock, Hayhurst states that:

You must include sufficient examples to justify a sound prediction that everything falling within the scope of the claims will have the promised utility.¹⁰¹

The question is whether Mr. Hayhurst intended the word “must” to mean “must as a matter of law” or “must as a matter of good practice.” This question can be answered by examining the case cited by Mr. Hayhurst as support for his proposition, *Olin Mathieson Chemical Corp. v Biorex Laboratories Ltd.*¹⁰²

67. *Olin Mathieson* was cited with approval by the Supreme Court of Canada in both *Monsanto* and *AZT*.¹⁰³ Mr. Dimock asserts that *Olin Mathieson* stands for the proposition “that there existed an obligation to properly support a sound prediction within the patent specification.”¹⁰⁴ That is incorrect. In fact, *Olin Mathieson* stands for the contrary proposition. The patent in *Olin Mathieson* stated the use that could be made of the compounds, but provided no evidence at all to support that statement of utility.¹⁰⁵ The factual basis for the sound prediction was drawn from various sources, none of which were found in the patent itself. In

¹⁰¹ W.L. Hayhurst, “Disclosure Drafting” (1971) 28 PTIC Bull (7th) 64, at 77-78 (R-164), quoted in the Dimock Report at ¶¶ 123, 149.

¹⁰² *Olin Mathieson Chemical Corp. v Biorex Laboratories Ltd.*, [1970] R.P.C. 157 (Ch D) (C-461).

¹⁰³ Cited with approval in *Monsanto*, at 1114-15 (C-61) and in *AZT*, at ¶ 60 (C-213). Mr. Dimock at ¶ 150 also quotes to the same effect another article by Mr. Hayhurst, “Annual Survey of Canadian Law – Industrial Property” (1979), 11 OTTAWA L. REV. 391, at p. 427 (R-198). That article cites no authority at all on this point.

¹⁰⁴ Dimock Report at ¶ 149 (original emphasis).

¹⁰⁵ See *Olin Mathieson Patent*, Patent GB 857,547, available from the European Patent Office online search facility Espacenet at <http://worldwide.espacenet.com/numberSearch> (C-462). The utility is described in the disclosure at p. 1, col 2, line 79 - p 2, col 1, line 16.

particular, one fact which the court relied on was that all of the claimed compounds which the patentee had made and tested had been shown to have therapeutic activity.¹⁰⁶ This is exactly the type of evidence that, under current Canadian law, would have to be disclosed in the patent itself in order to be considered as support for a sound prediction of utility. The court in *Olin Mathieson* not only considered this evidence, but considered it of “great importance,” even though it was not disclosed in the patent.¹⁰⁷

b) *Monsanto*

68. The 1970s *Monsanto* case, also cited by Mr. Dimock as evidence that prior law required disclosure of the factual basis for a sound prediction of utility, does not support his point. While the decision of the Patent Appeal Board, which is discussed at length by Mr. Dimock,¹⁰⁸ can fairly be read as imposing such a requirement, the Board’s position was rejected by the Supreme Court.

69. Mr. Dimock suggests that the Supreme Court overturned the Patent Appeal Board only because it disagreed with the Board’s view that the disclosed factual basis was insufficient to support a patent.¹⁰⁹ This is incorrect. The Supreme Court reversed based on its holding that, as a matter of law, an attack based on lack of utility must be supported by evidence of lack of utility.¹¹⁰ Stated otherwise, the burden is on the patent office to disprove utility, not on the patent applicant to prove it.

¹⁰⁶ *Olin Mathieson*, at 195 (C-461). Other evidence referred to by the court, such as prior patents and a textbook (see *ibid* at 194) were common general knowledge and so would not have to be disclosed even under current Canadian law. The court also placed great weight on expert evidence introduced at trial, and not disclosed in the patent, regarding the effect of a particular chemical substitution (*ibid* at 195). It is not clear whether this was common general knowledge. However, there was no express finding on this point, and it is therefore clear that Graham J.’s holding turned only on the evidence being introduced at trial, and not on it being common general knowledge. Moreover, it is clear that the result of the testing of the compounds was not common general knowledge.

¹⁰⁷ *Olin Mathieson*, *ibid* at 195 (C-461).

¹⁰⁸ Dimock Report at ¶¶ 128-33.

¹⁰⁹ Dimock Report at ¶¶ 135-36.

¹¹⁰ *Monsanto*, at 1122 (C-61); similarly, at 1121 (original emphasis), “In the instant case, the Board, in spite of a complete absence of any evidence of unsoundness of the prediction, deny the claims and would in the end limit them to the area of *proved utility* instead of allowing them to the extent of *predicted utility*. In my view this is contrary to s. 42 of the Patent Act.”

70. Moreover, the Supreme Court in *Monsanto* relied on *Olin Mathieson* as correctly stating the law of sound prediction.¹¹¹ As discussed above, the factual basis for the sound prediction in *Olin Mathieson* was not disclosed in the patent. While Mr. Dimock asserts that the Court in *Monsanto* “emphasized that a sound prediction must not go beyond the consideration provided by the disclosure,”¹¹² the Court in fact quoted *Olin Mathieson* as saying:

If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so.¹¹³

This simply says that the prediction must in fact be sound; it does not say, or even suggest, that the data supporting that prediction must be disclosed in the patent.

71. The Court in *Monsanto* also said:

[I]f, when attacked (for invalidity), he survives this risk successfully, then his claim does not go beyond the consideration given by his disclosure, his claim is fairly based on such disclosure in these respects, and is valid.¹¹⁴

Mr. Dimock apparently infers from this statement that the factual basis for the prediction of utility must be disclosed in the patent.¹¹⁵ This is, however, a mischaracterization of the meaning of the “consideration given by his disclosure.” This disclosure referred to by the Court is simply the traditional requirement of how to make and use the invention, which, as discussed above, can be satisfied without disclosing any evidence of utility in the patent itself.

c) *AZT*

72. As Mr. Dimock acknowledges, the Supreme Court in *AZT* was silent as to what constitutes “proper disclosure” in the context of sound prediction,¹¹⁶ but he infers that because

¹¹¹ *Monsanto*, at 1115 (C-61).

¹¹² Dimock Report at ¶ 136.

¹¹³ *Monsanto*, at 1115 (C-61), quoting *Olin Mathieson*, at 193 (C-461), quoted with emphasis in the Dimock Report at ¶ 136.

¹¹⁴ *Ibid.*, emphasized in the Dimock Report.

¹¹⁵ Dimock Report at ¶ 136.

¹¹⁶ Dimock Report at ¶ 125.

disclosure was not at issue between the parties, “the patent agents for Wellcome Foundation must have recognized the requirement to disclose the underlying facts and line of reasoning in the disclosure.”¹¹⁷ The proper inference is to the contrary. The Supreme Court summarized evidence relied on by the trial judge as establishing sound prediction, and it is clear that some of this evidence was not disclosed or not fully disclosed within the patent.¹¹⁸ Nor was all the evidence relied on by the trial court disclosed in the patent.¹¹⁹

73. Certainly the patent did disclose, or at least reference, some important elements of the factual basis for the prediction of utility, and it is possible that the information that was disclosed in the patent could have formed a sufficient basis for a sound prediction by a person skilled in the art. However, absent an express finding by the trial judge, this is simply speculation. It is clear that the full factual basis for the prediction considered by the courts was not disclosed in the patent. From this we must infer, contrary to Mr. Dimock’s assertion, that the patent agents for Wellcome Foundation did *not* recognize that there was any such requirement. This is because no disclosure requirement for sound prediction existed at the time the patent was drafted.

¹¹⁷ *Ibid.*

¹¹⁸ The Wise-Burchall report, noted by the Supreme Court in *AZT*, at ¶ 73(i) (C-213), included studies on drug metabolism in rats, pigs, chickens, sheep and calves which were not disclosed. The “preliminary testing on HeLa Alpha-DNA polymerase” (referred to *ibid* at ¶ 73(i)) was not disclosed, or at least was not fully disclosed. Glaxo/Wellcome’s experience with other nucleoside analogues (referred to *ibid* at ¶ 73(ii)) suggesting that it was likely that AZT would be absorbed by oral administration, was not disclosed. Further, the key *in vitro* test which was central evidence to establishing a sound prediction of utility (carried out by Drs. Samuel Broder and Hiroaki Mitsuya using the so-called ATH8 cell line) was described only in general terms and the specific nature of the ATH8 cell line itself was not disclosed. This is almost certainly because the development of the ATH8 line was itself an important breakthrough in HIV/AIDS research and the inventors sought and obtained a patent on the cell line itself soon after the application for the AZT patent. They would not have been able to do so if the cell had been disclosed in the AZT patent.

¹¹⁹ The trial court spent several paragraphs discussing murine assays using the Friend Leukemia Virus (FLV) and the Harvey Sarcoma Virus (HSV): *AZT FCTD*, at ¶¶ 113-116 (C-213). Neither of these assays was disclosed, even though the results were important enough that the researcher involved (Martha St. Clair) was named as one of the inventors.

(iii) The Post-AZT Interpretations Indicate that the Heightened Disclosure Requirement Was New and Uncertain

74. Mr. Dimock’s assertion that there was a long-standing requirement to disclose evidence of sound prediction in the patent is also inconsistent with post-AZT developments in the case law. As noted above, the AZT decision was ambiguous as to whether the cut-off date for the admissibility of evidence to establish a sound prediction was the priority date of the patent or the filing date of the patent in Canada. Subsequent decisions established the filing date as the relevant cut-off.¹²⁰ In those cases, the question was only important because there was evidence in support of a sound prediction of utility that came after the priority date and that was not disclosed in the patent. If that evidence was not admissible in any event due to a longstanding rule that evidence to support a sound prediction must be disclosed in the patent itself, then it would have been a moot point as to whether the filing date or the priority date was the correct cut-off. Indeed, in both decisions establishing the filing date as the correct cut-off point, it is clear that the court considered evidence that was not disclosed in the patent itself when examining whether utility was based on a sound prediction.¹²¹

75. In my first Report, I noted that *Raloxifene* was the first decision to interpret AZT in a manner that introduced the heightened disclosure requirement for utility based on a sound prediction.¹²² Mr. Dimock acknowledges that “On first blush, *Raloxifene* appears to be somewhat controversial,” but he asserts that it “follows the same principles applied more than 25 years prior in *Monsanto*.”¹²³ As discussed, this is incorrect; *Monsanto* did not establish a requirement to disclose the factual basis for sound prediction in the patent itself.

¹²⁰ See *supra*, at ¶ 62.

¹²¹ In *Aventis* (C-209), the patent claimed the anti-hypertensive compound ramipril. The evidence in question was work formulating and testing the claimed compounds that had been carried out after the priority date but prior to filing. *Ibid* at ¶ 81. That evidence is not disclosed anywhere in the patent: see Canadian Patent 1,341,206. The court, *ibid* at ¶ 129, also considered a rat assay that was not disclosed in the patent. In *Quinapril* (C-215), the Court of Appeal affirmed the holding in *Aventis* that the correct date for assessing the soundness of a prediction was the filing date, not the priority date, and then affirmed the holding that the prediction of utility was sound, based in part on result of testing in rats that had been received after the priority date but before the filing date.

¹²² Siebrasse First Report at ¶ 86.

¹²³ Dimock Report at ¶ 140.

76. Moreover, if it were true that *Raloxifene* follows the principles set out in *Monsanto*, then it is curious that Justice Hughes, the trial judge in *Raloxifene*, who was a patent practitioner with decades of experience before being appointed to the bench, relied solely on *AZT* in holding that the factual basis for a sound prediction must be disclosed in the patent, without citing *Monsanto*.¹²⁴ The Court of Appeal, in affirming, did the same.¹²⁵ In fact, in almost 30 years since *Monsanto* was decided, no court has ever held that *Monsanto* stands for that principle that heightened disclosure is required where utility is based on a sound prediction.

77. Moreover, the *Raloxifene* interpretation of *AZT* has sparked judicial controversy. The concurring reasons in the Court of Appeal decision in *Plavix* question whether *AZT* is a proper basis for “the heightened level of disclosure applied in recent case law.”¹²⁶ This explicitly acknowledges that the heightened disclosure requirement is recent, and traceable at most to *AZT*. The concurrence goes on to suggest that this heightened disclosure requirement should apply only to “new use” patents.¹²⁷ Similarly, the trial judge in the *Nexium* decision, Rennie J., who has since been elevated to the Court of Appeal, has also traced the heightened disclosure requirement to *AZT*, and concluded that on the proper interpretation of that decision, the heightened disclosure requirement should be limited to “new use” patents.¹²⁸ If the obligation to disclose the evidence of sound prediction in the patent itself were long-standing, surely the scope of the requirement would already have been addressed and would not need to be extensively discussed within the jurisprudence.

78. It is not surprising that there has been controversy over the new and additional disclosure requirement. Mr. Dimock notes that the supposed rationale for the requirement is that, without such disclosure, no “hard coinage” has been paid for the patent right or privilege.¹²⁹ This rationale does not withstand scrutiny. As discussed above, the “hard coinage” of disclosure is

¹²⁴ *Raloxifene* FC, at ¶¶ 163-64 (C-115).

¹²⁵ *Raloxifene* FCA, at ¶¶ 14-15 (C-119).

¹²⁶ *Plavix*, at ¶ 132 (C-47).

¹²⁷ *Ibid* at ¶ 134.

¹²⁸ *AstraZeneca Canada Inc. v Apotex Inc.*, 2014 FC 638, ¶¶ 139-61 (C-48).

¹²⁹ Dimock Report at ¶ 145.

paid when the patentee discloses an invention; whether or not proof or evidence that this is so is included in the patent. This rationale is also entirely undermined by the fact that disclosure of the basis for utility is not required if utility is demonstrated,¹³⁰ but only when utility is established by sound prediction.

79. If consideration for the grant of a patent included disclosure in the patent of evidence establishing utility, then the duty to disclose the factual basis would extend to demonstrated utility, as well as utility based on sound prediction. But in current Canadian law the disclosure requirement applies only in the context of the sound prediction analysis. Moreover, there has never been any obligation to disclose evidence of novelty or non-obviousness. The “hard coinage” argument therefore provides no justification for an obligation to disclose evidence of utility.

III. Conclusion

80. Mr. Dimock’s report treats each aspect of the Promise Utility Doctrine as a distinct requirement and attempts to undermine the impact that the doctrine has had in Canada by asserting that these aspects existed in prior Canadian law. His report does not support this, and does not respond at all to a key assertion in my first Report, which is that all aspects of the doctrine operate together to create an additional barrier to establishing utility that is higher than the sum of its parts.

81. For pharmaceutical patents in particular, the impact of the doctrine has been dramatic. For reasons explained in my first Report, pharmaceutical patents are normally filed when the applicant has some evidence of utility, but long before the clinical trials necessary to establish therapeutic efficacy in humans. Nonetheless, the promise of the patent may have the effect of raising the standard for utility to that of clinical efficacy. It is normally possible to demonstrate therapeutic efficacy at the time of trial, because it is the patents relating to the commercially valuable pharmaceuticals that are litigated, and so such pharmaceuticals are clearly useful in fact. The patentee may be able to establish a scintilla of utility based only on the pre-

¹³⁰ See e.g. *Olanzapine (No. 1)*, at ¶ 74 (C-46); *Novopharm Ltd. v Pfizer Canada Inc.*, 2010 FCA 242, ¶ 80 (C-464); *Pfizer Canada Inc. v Ranbaxy Laboratories Ltd.*, 2008 FCA 108, ¶¶ 56-64, 67 C.P.R. (4th) 23 (C-235); *AstraZeneca Canada Inc. v Apotex Inc.*, 2014 FC 638, ¶ 130 (C-48).

filing evidence, because that standard is so low; but to establish therapeutic efficacy based on pre-filing evidence alone may be impossible. This means that the patentee's only option under current Canadian law may be to try to establish a sound prediction of therapeutic efficacy using pre-filing evidence alone; but even if the patentee actually had sufficient data at the time of filing to establish a sound prediction of therapeutic efficacy, its case may still fail if that evidence was not disclosed in the patent itself.

* * *

Done at FREDERICTON, NB on 10 SEPT 2015

[signed]

Norman V. Siebrasse